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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/904,782 | 07/13/2001 | Suresh K. TiKoo | 293102002900 | 1838 |

25226 7590 01/26/2004
MORRISON & FOERSTER LLP
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EXAMINER

SCHEINER, LAURIE-A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1648

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DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/904,782

Applicant(s)
Tikoo, S.

Examiner
Laurie Scheiner

Art Unit
1648



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 1, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above, claim(s) 9, 12, 13, 22-28, and 31-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 11, 14-21, 29, and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 & 3 6) ☐ Other:

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Applicant's election of Group I (claims 1-8, 10, 11, 14-21, 29 and 30) is acknowledged. Claims 9, 12, 13, 22-28 and 31-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7. Applicant's comments with respect to the traversal are not persuasive. Applicant fails to distinctly and specifically point out the supposed errors in the restriction requirement. That is, applicant has merely offered (independent of the reasons given for the restriction requirement) a position on the grouping of the claims. That is, an actual direct response to the specific reasons for restriction have not been set forth. The traversal is on the ground(s) that rejoining Groups A-D will not create a search burden. Groups A-D will not be combined as requested since the Groups are respectively limited to different compositions. Regarding applicant's reasons for the traversal, it is asserted that a search burden is not the sole consideration for determining restriction between inventions. Due to art volume, search and examination of all four transgenes would impose an undue burden for the examiner.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-8, 10, 14-16, 18-21 and 29 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Matthews et al. (Journal of General Virology (1999) 80, 345-353).

Matthews et al. clearly teach mammalian cell lines in which an adenovirus vector with a promoter-intron expression cassette expressing a rabies (RNA virus) protein at much higher levels than vectors lacking the intron. Moreover, preliminary studies in mice indicate that a very high level of rabies virus-neutralizing antibody can be induced by the intron-containing vectors following intraperitoneal injection.

Claims 1-8, 10, 11, 14-21, 29 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Mehtali et al. (Patent No. 6,479,290 B1).

Mehtali et al. clearly teach the improvement of expression of heterologous genes by an intron sequence. Pharmaceutical preparations containing the transgene containing adenoviral vectors are also taught.

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Claims 1-8, 10, 11, 14-21, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Lusky et al. (WO9961638).

Lusky et al. teach adenoviral vectors having an intron 5' to a heterologous transgene wherein said 5' intron results in an increased expression of the heterologous insert. BAV3 is also clearly taught.

Claims 1-8, 10, 11, 14-21, 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by FR2642767.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Scheiner, whose telephone number is (703) 308-1122. Due to a flexible work schedule, the examiner's hours typically vary each day. However, the examiner can normally be reached Monday thru Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

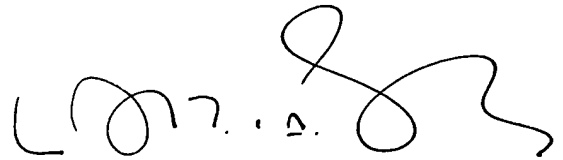
Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward the following central fax number: (703) 872-9306.

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Laurie Scheiner/LAS
January 14, 2004

A handwritten signature in black ink, appearing to read 'Laurie Scheiner' with a stylized flourish at the end.

**LAURIE SCHEINER
PRIMARY EXAMINER**